UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JANELLE SCHNULLE, Plaintiff, v. SOMATICS, LLC, Defendant.	Case No.: **COMPLAINT FOR DAMAGES** **(Jury Trial Demanded)**

COMPLAINT

Plaintiff JANELLE SCHNULLE, by and through her counsel, brings this Complaint against Defendant SOMATICS, LLC, and alleges as follows:

NATURE OF THE ACTION

1. This common-law products liability, negligence and fraud action arises out of serious and debilitating cognitive injuries that plaintiff, JANELLE SCHNULLE ("Plaintiff" or "Ms. Schnulle") sustained as a result of undergoing multiple rounds of electroconvulsive shock treatment with a device manufactured and distributed by defendant, SOMATICS, LLC ("Defendant" or "SOMATICS").

2. The injuries Ms. Schnulle sustained as a result of SOMATICS' shock treatment device, include but are not limited to, brain damage, neurocognitive injuries, severe permanent memory loss, significant decline in his ability to learn and recall information, a disruption and decline in his ability to encode new information, diminished quality of life, additional physical, physiological, psychological and emotional injuries and harms, and lost wages and earning capacity.

3. Plaintiff alleges that SOMATICS negligently and intentionally concealed and failed to adequately disclose and warn about risks, including but not limited to, brain damage and

permanent neurocognitive injuries associated with their shock treatment device. In addition to concealing risks, SOMATICS intentionally, recklessly and overtly misrepresented the safety and efficacy of the shock therapy device.

PARTIES AND VENUE

4. Plaintiff, Janelle Schnulle, is an adult and a resident and citizen of the state of Texas.

5. At all relevant times, defendant SOMATICS is and was a limited liability company formed and existing under the laws of the State of Florida with its principal place of business at 710 Commerce Dr., Unit #101, Venice, FL 34292.

6. SOMATICS is the manufacturer, labeler, promoter, and distributor of the "Thymatron" Electroconvulsive Therapy ("ECT") shock device. An ECT shock device is a device used for treating severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head. An ECT shock device, in lay terms, is used to administer "shock treatment."

7. Upon information and belief, SOMATICS regularly conducts and transacts business in Missouri and has sold the Thymatron ECT devices to multiple hospitals and medical facilities in Missouri, including but not limited to, the medical facility where Plaintiff received her ECT treatment, and SOMATICS has generated revenue from sales within Missouri. This Court has personal jurisdiction over SOMATICS because it has sufficient minimum contacts in Missouri to render the exercise of jurisdiction by this Court proper.

8. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendant are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2). A substantial portion of the events and omissions giving rise to this lawsuit occurred in this District and the Court has personal jurisdiction over each of the parties as alleged throughout this Complaint.

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GENERAL ALLEGATIONS

A. Brief History of the Discovery of ECT

10. Electroconvulsive therapy ("ECT") is the practice of inducing grand mal motor seizure through application of electricity to the brain. In the late 1930's, after observing slaughterhouses apply electricity to pigs to render them manageable for slaughter, Ugo Cerletti and Lucino Bini, two scientists at the University of Rome thought that electricity could be used to treat schizophrenia. Scientists at the time theorized (incorrectly) that *seizures* could potentially cure or decrease the symptoms of schizophrenia and thus were considering using electricity to induce grand mal seizure with the hopes of curing schizophrenia.

11. Cerletti and Bini began to test their theory by applying electricity to dogs and it was noted by Bini that the majority of the dogs died during the experiment.

12. In April 1938, after having sacrificed sufficient dogs, Cerletti and Bini applied ECT to the first human patient. A 40-year old Italian man who had been found wandering the train station in Rome and speaking gibberish was brought to the University of Rome and had 70 volts of electricity applied to his temple by Cerletti. It has been reported that, while the scientists were deliberating whether they should apply a second higher voltage, the patient pleaded "*Non una seconda! Mortifera!*" ("not again it will kill me!"). Seeing success that the man was speaking lucidly as opposed to his initial gibberish, Cerletti applied a second and higher voltage (110 volts) of electricity. The scientists reported that, after the application of the electricity, the patient became more lucid and was able to speak coherently. The patient was administered approximately a dozen more sessions of ECT and was eventually discharged but subsequently lost to follow-up.

13. In May 1938, Cerletti publicly presented his results on the use of ECT on this patient at the Medical Academy of Rome. Shortly thereafter and starting in the early 1940s, ECT began to gain acceptance for the purported treatment of schizophrenia (and eventually other psychiatric ailments) across Europe and in the United States.

14. It may come as a surprise to some, but ECT shock treatment is still presently prescribed in the United States for various psychological disorders including, but not limited to,

depression, bipolar disorder, schizophrenia and catatonia and is used on patients of all ages, including children and the elderly. In an effort to veil the image of patients jolting, jarring and convulsing during the procedure, patients are now placed under anesthesia during the procedure, but as outlined herein, while the use of anesthesia may mask the image of overt convulsions, the devastating permanent side-effects of ECT on the body and the brain remain the same, and in some cases, exacerbated.

B. Regulatory History of ECT

15. Prior to 1976, medical devices could be marketed without review by the U.S. Food and Drug Administration (FDA). Spurred by the increased technological complexity of devices and mounting disclosures of shortcomings involving pacemakers, intrauterine devices, and intraocular lenses, Congress enacted the comprehensive Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. The primary purpose of the amendments was to ensure that new devices were safe and effective before they were marketed." Kessler DA et al., *The Federal Regulation of Medical Devices*, THE NEW ENGLAND JOURNAL OF MEDICINE, August 8, 1987.

16. The Federal Food, Drug, and Cosmetic Act (hereinafter, the "Act") (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (the "1976 amendments") (Public Law 94-295), the Safe Medical Devices Act of 1990 (the "SMDA") (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 ("FDAMA") (Public Law 105-115), the Medical Device User Fee and Modernization Act ("MDUFA") (Public Law 107-250) and the medical device provisions of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law 110-85), along with the applicable regulations in the Code of Federal Regulations, established a framework for the regulation of medical devices intended for human use.

17. Congress established three classes of devices, based on the regulatory requirements needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are Class I, Class II, and Class III. Class I devices present no unreasonable

risk of illness or injury and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful and are subject to general controls, but FDA in addition has authority to require that such devices comply with other "special controls" or performance standards. 21 U.S.C. 360c(a)(1)(B). Class III devices present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C)(ii)(II).

18. Examples of Class I devices include bandages and enema kits. Examples of Class II devices include condoms, some pregnancy test kits and powered wheelchairs. Examples of Class III devices include pacemakers and breast implants.

19. In drafting the 1976 amendments, Congress divided medical devices in two different ways: (1) according to three classes noted above — class I, II, or III, and (2) according to seven basic categories — pre-amendment, post-amendment, substantially equivalent, implant, custom, investigational, and transitional. The current regulatory scheme involved weaving these two methods of subdivision into a workable statutory framework.

20. New devices, including any devices that were not in commercial distribution prior to May 28, 1976, generally referred to as post-amendments devices, are classified automatically by statute (section 513(f) of the Act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require a manufacturer to submit to FDA a premarket approval application, unless or until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the Act (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval.

21. Before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" ("PMA" may refer to either premarket approval or premarket application) from FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, the manufacturer must submit information to FDA in a premarket approval application that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C),

360e(a), (c), and (d); 21 C.F.R. §§ 814.

22. PMA is the most detailed type of device marketing application and review required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). PMA requires clinical testing to assure safety and effectiveness.

23. However, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as pre-amendments devices, are classified after FDA has: (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

24. A loophole known as the "grandfathering" provision permits Class III devices that were on the market before the 1976 Medical Device Amendment's enactment to remain on the market until FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In addition, Congress created another loophole which permits new manufacturers to distribute similar devices by showing through a premarket notification process that their new devices are "substantially equivalent" to grandfathered devices. 21 U.S.C. 360e(b)(1)(B). This premarket notification process is known as the "Section 510(k) process," referring to the applicable section of the Act (21 U.S.C. 360(k)). A device is "substantially equivalent" to a grandfathered device only if, among other things, the device has the same "intended use" as the predicate device. 21 U.S.C. 360c(i)(1)(A).

25. It is this grandfathering *loophole* that has allowed the SOMATICS Thymatron ECT device onto the market. Specifically, because various ECT machines had been on the market prior to the 1976 enactments of the Medical Device Amendments, SOMATICS in or about 1984, was able to obtain grandfathering clearance for its ECT device without submitting a premarket approval application (PMA) and without having to submit *any* clinical trials

concerning the safety and efficacy of its ECT device.

26. Notably, in September 1979, the FDA issued a Rule classifying ECT machines as Class III devices and requiring all manufacturers of ECT devices to submit a PMA application that includes information concerning safety and effectiveness tests for the devices. *See* 44 Fed.Reg. 172, Sept. 4, 1979, pages 51776-77. However, after pressure from the American Psychiatric Association and in light of the fact that not a single ECT manufacturer submitted the requested PMA, the FDA chose not to enforce its Rule/Order.

27. Thereafter, beginning in 1984, the FDA allowed new ECT manufacturers, including SOMATICS, to simply submit a 510(k) notification (which does not require showing of safety or effectiveness nor does it require presentation of any clinical trial data) to obtain clearance to sell its ECT device.[1]

28. Between the late 1970s and the time that Ms. Schnulle received her last ECT treatments in 2016, the FDA had oscillated numerous times as to what classification should apply to ECT machines and unfortunately never enforced any of its Rules that had required for PMA approval for ECT machines. This has resulted in the ECT machines currently on the market, including SOMATICS' Thymatron ECT Device, never being subjected to a full FDA PMA review, SOMATICS has never conducted a clinical trial to demonstrate the safety and efficacy of the Thymatron ECT device (or any other ECT device) and SOMATICS has never submitted clinical trials to demonstrate the safety and effectiveness of the Thymatron ECT device.

29. Contrary to SOMATICS' false advertisements, during the relevant time period and presently, the FDA's position has been that "[t]he long-term safety and effectiveness of ECT treatment *has not been demonstrated*." Emphasis added. Moreover, as previously mentioned, to date SOMATICS has not undertaken a single clinical trial to test the safety and efficacy of its

[1] The distinction between PMA approval and 510(k) clearance is significant. The Supreme Court has noted, the PMA approval process usually takes the FDA 1,200 hours to complete, whereas the 510(k) review is completed by the FDA in an average of only 20 hours. Moreover, the 510(k) notification process "requires little information, rarely elicits a negative response from the FDA and gets processed very quickly." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

ECT device. Nonetheless, during the relevant time period and to this date, SOMATICS in order to facilitate sales and in order to encourage medical professionals to recommend ECT treatment and in order to convince patients to undergo ECT treatment, states on its website that "ECT remains the safest and most effective treatment for severe depression" – knowing fully that its promotional statements are false and misleading as there is no support nor any clinical trials supporting such an endorsement of safety and efficacy of its ECT device.

30. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately suspended."[2]

C. Defendant's Failure to Adequately Test, Investigate, Report and Study the Safety and Efficacy of its ECT Device

31. Dr. Abrams, the founder, owner and member of SOMATICS, has testified under oath that SOMATICS has *never* performed any studies or tests to analyze the long-term side effects associated with ECT. Dr. Abrams further testified that it is not SOMATICS' business to conduct such safety studies on its ECT device.

32. Furthermore, SOMATICS has failed to comply with its pharmacovigilance requirements and have failed to comply with its mandatory duty of timely investigating, evaluating, and reporting adverse events to the FDA. Under the applicable federal regulations, SOMATICS, as a device manufacturer, had an affirmative responsibility to timely report to the FDA any serious injury that the manufacturer becomes aware of, *from any source* (including, by

[2] John Read et al., *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).

way of example, case reports published in scientific articles or other literature), that suggests that the manufacturer's device may have caused or contributed to serious injury. *See* 21 C.F.R. §§ 803 *et seq*.

33. In addition, as a medical device manufacturer, SOMATICS had a duty to investigate all complaints of adverse events (from any source) to determine whether a report should be submitted to the FDA. *See* 21 C.F.R. §§ 803.17, 803.18 & 820.198. SOMATICS also failed to undertake any such efforts to investigate serious adverse events (such as brain injury or permanent memory loss) that it became aware of through the scientific literature or other sources.

34. The adverse event reporting requirements that apply to device manufacturers are essential for the FDA as well as medical professionals to learn of adverse events as well as the potential frequency of adverse events. The medical device adverse reports that are reported by manufacturers and other stakeholders are publicly published by the FDA on its Manufacturer and User Facility Device Experience ("MAUDE") database which is accessible to the medical community and stakeholders.

35. On multiple occasions, for example in the mid-1990s when the FDA required ECT manufacturers to submit data and information about their respective ECT devices, SOMATICS failed to submit any information to the FDA concerning reportable safety risks and adverse events.

36. Likewise, in 2009, in response to FDA's inquiries, SOMATICS informed the FDA that, in the 25-years since obtaining clearance for its Thymatron device, "there has been no occurrence of a reportable adverse event (death or serious injury) related to the use of a Thymatron ECT device…" SOMATICS made this statement notwithstanding the myriad of medical journal publications that discussed adverse events associated with ECT machines, including the Thymatron device. Indeed, SOMATICS made this bogus representation notwithstanding the fact that the FDA had contemporaneously received public comments from medical professionals and the public in response to the same inquiry that included *hundreds* of complaints of cognitive impairment, brain damage and more than a hundred complaints of death

associated with ECT devices.

37. Since obtaining clearance in 1984, in response to each and every one of the thousands of instances of SOMATICS becoming aware of information reasonably suggesting death or serious injury associated with its device, SOMATICS conducted no investigation and failed to undertake any pharmacovigilance duties.

38. As a result of the SOMATICS' conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, failing to warn of known and knowable risks, and failure to comply with the statutory and common law duties under state law running parallel to such requirements, during the relevant time period, the Thymatron ECT devices were manufactured, sold, distributed and remained in use without adequate testing, without adequate dissemination of reliable information and data as to safety and effectiveness of the ECT device and without adequate warnings concerning serious and significant risks, including but not limited to risks of brain damage, brain injury, neurocognitive impairment, encephalopathy, structural brain changes, permanent cognitive impairment and permanent memory loss.

D. Defendant Knew, or Should Have Known, About Serious Injuries, Including Brain Injury and Permanent Memory Loss Associated With its ECT Device, Yet it Failed to Issue Timely Warnings and Instead Falsely Downplayed the Risks to Promote Sales

39. Adverse events have regularly resulted from administration of ECT shock treatment since ECT's inception in 1938 such as to make it virtually impossible that any ECT manufacturer could escape the obligations to investigate, report and warn about such adverse events. For example, from the early days of ECT to the present day, various psychiatric experts have documented brain damage correlated with ECT. A vocal "ECT survivor community" has been voicing their objection to the continued use of shock treatment for decades. Moreover, during FDA hearings between 2009 and 2011 in which the FDA opened a public docket seeking reports of adverse event complaints, ECT patients submitted thousands of adverse event complaints, hundreds of which alleged serious brain injury. SOMATICS became aware of these

adverse event allegations by virtue of participating in those hearings, and therefore the hearings invoked Defendant's statutory duty to investigate, evaluate, and if necessary independently and more fully report the complaints to the FDA so that they are fully researched and reflected in the MAUDE database. However, at all times relevant to this action, there were no manufacturer-submitted adverse event reports in FDA's MAUDE database corresponding to those adverse event allegations, illustrating SOMATICS' continuous and intentional failure to investigate and/or report adverse events to the FDA.

40. "The Electroshock Quotationary" was published in 2006.[3] It recounts an eighty-year history of serious adverse events including permanent brain damage resulting from ECT shock treatment, as well as the formation of patient advocacy groups united in their continued opposition to ECT shock treatment. Moreover, it references testimony and studies by U.S. psychiatrists, in which the psychiatrists opine that ECT inherently damages the brain. No account of injury resulting from ECT shock treatment referenced in the Electroshock Quotationary were investigated and reported by SOMATICS.

41. Many studies have suggested or documented reasonably known brain injury resulting from ECT shock treatment. For example, a study in Archives of General Psychiatry documented that cerebral atrophy was significantly more common in those patients who had ever received ECT.[4]

42. A brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.[5]

43. A study relating MRI scans of patients demonstrated a strong correlation between

[3] LEONARD ROY FRANK, THE ELECTROSHOCK QUOTATIONARY (2006), http://www.endofshock.com/102C_ECT.PDF.
[4] Weinberger et al., *Structural Abnormalities in the Cerebral Cortex of Chronic Schizophrenic Patients*, 36 ARCHIVES GEN. PSYCHIATRY, 935-39 (1979).
[5] Calloway et al., *ECT and Cerebral Atrophy: A CT Study*, 64 ACTA PSYCHIATRICA SCANDINAVICA 442-45 (1981).

the numbers of previous ECT treatments to loss of brain tissue.[6]

44. Another study found that ECT recipients were twice as likely to have a measurable loss of brain tissue in the front area of the brain and a tripling of the incidence of a loss of brain tissue in the back of the brain.[7]

45. Finally, another study documented intra-cranial bleeding resulting from ECT shock treatment administered using current ECT devices.[8]

46. SOMATICS, however, remained willfully ignorant or otherwise intentionally failed to follow up or do any investigation on the adverse events in these and other similar published adverse events in an attempt to evade its mandatory reporting duties and keep from having to publicly admit its awareness that a risk of permanent brain damage is associated with the use of its ECT device.

47. SOMATICS, as a leading manufacturer and distributor of ECT devices, knew and certainly should have known about the potential risks of brain injury, permanent cognitive impairment and permanent memory loss associated with its Thymatron ECT Device. In addition to the various scientific journal articles, meta-analyses, and case reports addressed, *supra*, which raised these risk concerns, scientists testified in governmental proceedings concerning these brain injury risks and their mechanism of action. As way of example, Peter Sterling, Ph.D., a neuroscientist and professor at the University of Pennsylvania and ECT researcher, testified before the New York State Assembly on July 18, 2001 regarding the effects of ECT on the brain, and in his testimony to the New York Assembly he stated:

> ECT unquestionably damages the brain, and there are a variety of mechanisms that lead to this damage. In the first place, the electroshock delivered to the skull is basically

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[6] Andreasen et al., *MRI of the Brain in Schizophrenia*, 47 ARCHIVES GEN. PSYCHIATRY, 35-41 (1990).

a. [7] R.J. Dolan et al., *The Cerebral Appearance in* Depressed *Subjects*, 16 PSYCHOL. MED., 775-79 (1986).

[8] Kulkarni & Melkundi, *Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review*, CASE REPORTS IN PSYCHIATRY (2012).

> similar to what you would get out of an electrical wall outlet, except that there is a transformer in the ECT machine that steps up the voltage…when this is done two or three times a week for weeks, it's just completely obvious that this is going to eventually cause some kind of brain damage…
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> Now the second point, source of brain damage for ECT is that it causes…grand mal epileptic seizures…and this causes an acute rise in blood pressure, well into the hypertensive range…And it frequently causes small…hemorrhages in the brain.
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> And wherever a hemorrhage occurs in the brain, nerve cells die, and they are not replaced. And so one can accumulate these hemorrhages over a period of treatments leading to brain damage.
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> A third thing that ECT does is to rupture the blood brain barrier. This barrier normally protects the brain from potentially damaging substances in the blood…breaching this barrier exposes nerve cells in the brain to chemical insults that can kill them…also leads…to swelling of the brain…swelling leads to local arrest of blood supply, to loss of oxygen…and to death of neurons.
>
> The fourth thing…is that ECT…causes neurons to release large quantities of …glutamate. Glutamate excites further neuronal activity…and this becomes a vicious cycle…Neurons literally…kill themselves from over activity…the key manifestation of this brain damage is retrograde memory loss….

48. Dr. Sterling's testimony was given during hearings by the New York Assembly which was considering introducing regulations concerning the use, assurance of informed consent and oversight of ECT procedures. As manufacturers of one of the two main ECT devices in the nation, SOMATICS either knew or certainly should have known about the Assembly hearings, the proposed legislation as well as the opinions and medical testimony publicly delivered to the Assembly, including the above opinions and testimony of Dr. Sterling which were directly quoted and referenced in the State Assembly's subsequent March 2002 Report on Electroconvulsive Therapy. SOMATICS, however, as with its lack of response to the myriad of other previous articles and scientific publications that had raised concerns about the use of ECT and brain injury, did not undertake any efforts to enhance their device warnings.

49. The true electrical current exposure and eventual brain damage risks ECT patients endure is perhaps best encapsulated by Kenneth Castleman, Ph.D., a Biomedical Engineer and former faculty member and Visiting Committee Chairman of the Department of Electrical and

Computer Engineering at Caltech, who issued a report in a previous ECT litigation involving allegations of brain injury. In his report, Dr. Castleman went through the electrical currents an ECT patient receives and summarized it as follows:

> So, to put this all in perspective, the amount of electric current that an ECT machine puts through a patient's head is about 200 times what is considered dangerous for ground fault leakage, approximately 100 times what Tasers, cattle prods, and electric fences use, about the same as what is used for stunning pigs, and roughly one-fifth as much as the electric chair. In addition, the amount of voltage applied to the head (460 volts) is about 400 times what is required to damage a single brain cell. Clearly this amount of electricity has the potential to cause injury to the brain.

50. Notwithstanding the above alleged facts, during all times relevant to this action, SOMATICS never issued adequate warnings about the brain injury, permanent cognitive injuries and permanent memory loss associated with its ECT Thymatron Device.

51. Had SOMATICS issued warnings to medical providers concerning the risks of brain injury, permanent cognitive impairment and permanent memory loss as well as the other serious adverse events associated with the ECT Thymatron Device, medical providers would have heeded these warnings and, as is their fiduciary responsibilities, would have passed on those warnings to patients during the informed consent process. However, as a result of SOMATICS' negligent, reckless and fraudulent conduct, and its failure to issue adequate warnings, SOMATICS denied patients, including Plaintiff, the ability to make truly informed consent.

52. Sadly, in lieu of issuing appropriate warnings concerning the documented risks associated with ECT, including but not limited to brain damage, permanent cognitive impairment and permanent memory loss, SOMATICS instead prepared a "Patient Information Pamphlet" which it gave to doctors to give to all ECT patients, which downplayed any side effects, falsely stated that ECT does not cause brain injury, falsely stated that any memory loss issues are temporary and not permanent, falsely claimed that ECT actually improved memory and to further downplay the risks of ECT. Instead, the Pamphlet pinned any cognitive adverse events to the patients' underlying condition, other medications and aging.

53. It was not until sometime after October 2018 (after settling an ECT brain injury litigation and years after Ms. Schnulle had concluded her ECT treatment) that SOMATICS revised its website to issue *new* warnings about adverse events associated with ECT and its Thymatron device – SOMATICS *now* for the first time warns on its website that, "in rare cases" ECT "patients may experience permanent memory loss or permanent brain damage."

54. Somatics also revised its User Manual for the Thymatron device in 2019, which now states in relevant part:

> [Practitioners] should also be familiar with the FDA final order of December 26, 2018 (83 FR 66103-66124). Clinicians who administer ECT should participate in continuing education about ECT … It is essential that doctors planning to use the Thymatron System IV device read and follow the warnings and recommendations of the Task Force of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (APA, 2001), which states, in part, that **"A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations … in some patient self-reports of profound ECT-induced deficits may reflect objective loss of function … In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years …"**

Emphasis added.

55. Such warnings and indeed even more conclusive warnings concerning permanent memory loss and brain injury should have been given by SOMATICS to medical professionals and the public *decades ago* when such risks were first reported and were known to SOMATICS.

PLAINTIFF-SPECIFIC ALLEGATIONS

56. Plaintiff, Janelle Schnulle, underwent approximately 33 sessions of ECT shock treatment from approximately April 10, 2015 through January 29, 2016, administered by Eduardo Garcia Ferrer, M.D. and Frederick G. Hicks, M.D., at Mercy Hospital St. Louis in St. Louis, Missouri, with an ECT device manufactured and/or distributed by SOMATICS. The ECT treatments were prescribed for depression.

57. In obtaining Ms. Schnulle's consent, her treating psychiatrists and physicians,

likely unaware of ECT's risks of brain injury and permanent neurocognitive side effects (because SOMATICS had not issued such warnings and instead had overtly denied that such risks exist), did not provide Ms. Schnulle with any warnings concerning the risk of brain injury or permanent neurocognitive decline and injuries. Nor did Ms. Schnulle receive any warnings about the risks outlined herein and which SOMATICS knew about but failed to warn about, including for example, the fact that the safety and efficacy of ECT for long term use had never been tested, the fact that ECT presents a material risk of causing structural brain trauma including cell death, hippocampal damage, and subdural hematoma, in a way that wholly debilitates the patient with permanent cognitive impairment, such that many patients cannot live normal lives after receiving ECT shock treatment as well as the various other serious injuries and symptoms outlined in this Complaint.

58. Had Ms. Schnulle been warned concerning the risk of brain injury or permanent neurocognitive decline, she would not have consented to ECT treatment.

59. ECT did not generate improvement in Ms. Schnulle's symptoms. Instead of improving her symptoms, Ms. Schnulle's IQ diminished after ECT and she suffered significant impairment in her day-to-day functioning. Ms. Schnulle is often unable to complete basic math and feels confused and disoriented, such that she cannot socialize in ways she once could. Ms. Schnulle, formerly a fitness instructor, is no longer able to maintain gainful employment as a result of the side effects of ECT.

60. In sum, as a result of the repeated exposure to SOMATICS' ECT device, Ms. Schnulle has sustained numerous injuries, including but not limited to: neurocognitive injuries, impaired visual and verbal memory, severe short- and long-term memory loss, significant decline in her ability to learn and recall information, a disruption and decline in her ability to encode new information, loss of executive function, and additional physical, physiological, psychological, and emotional injuries and harms, as well as lost earnings and loss of earning capacity.

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COUNT I

NEGLIGENCE AGAINST DEFENDANT SOMATICS

61. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

62. At all relevant times, Defendant SOMATICS, LLC was the manufacturers, designers, distributors, sellers, and/or suppliers of the Thymatron ECT Device.

63. Defendant owed a duty to Plaintiff and the general public to use reasonable care in the researching, manufacturing, analyzing, testing, selling, advertising, promoting, distributing, labeling and marketing of its ECT devices, including the Thymatron ECT device.

64. Notwithstanding said duty of care, Defendant, individually, as well as through its agents, servants or employees, negligently, recklessly and carelessly:

a. Failed to provide adequate warnings to the medical community and the public about risks, dangers and side effects associated with the use of its ECT device, including but not limited to failing to warn about the risks of permanent brain damage, brain injury, permanent neurocognitive injury and permanent memory loss.

b. Failed to adequately research, test and analyze the safety of its ECT device.

c. Failed to adequately investigate the reports of serious adverse events, including but not limited to permanent memory loss, neurocognitive decline, death, burning and brain injury that it knew about or should have known about.

d. Failed to adequately report adverse events to the FDA.

e. Failed to comply with applicable federal laws and regulations governing medical device manufacturers, including but not limited to, The Federal Food, Drug, and Cosmetic Act (hereinafter, the "Act") (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (the "1976 amendments") (Public Law 94-295), the Safe Medical Devices Act of 1990 (the "SMDA") (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 ("FDAMA")

(Public Law 105-115), the Medical Device User Fee and Modernization Act ("MDUFA") (Public Law 107-250) and the medical device provisions of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law 110-85), along with the applicable regulations in the Code of Federal Regulations, including more specifically, but not limited to: 21 C.F.R. §§ 803.1 -803.23; 21 C.F.R. §§ 803.50-803.58; 21 C.F.R. § 820.198; and 21 C.F.R. §807.20.

f. Failed to inform and warn the medical community, patients and the public that the safety and efficacy of the use, in particular long-term safety and effectiveness of ECT treatment, has never been demonstrated.

g. Defendant falsely assured the medical community, patients and the public that "ECT remains the safest and most effective treatment for severe depression" when it knew or should have known that such a proclamation and assurance of safety and efficacy had never been demonstrated, nor are there any clinical trials to support the veracity of such a statement for the Thymatron ECT Device.

65. As a direct and proximate result of one or more of these aforementioned acts or omissions of Defendant, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement, and loss of a normal life. These losses are permanent.

COUNT II

STRICT LIABILITY AGAINST DEFENDANT SOMATICS

66. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

67. At the time the Thymatron ECT Device(s) (which were used during Plaintiff's ECT treatment between 2015 through 2016), left the control of the SOMATICS, it was defective and unreasonably dangerous when SOMATICS manufactured, designed, labeled, promoted and instructed practitioners, who is strictly liable for the injuries caused from its use.

68. The risks attendant to the Thymatron ECT Devices as designed, manufactured, promoted and sold by SOMATICS greatly outweighed any possible benefits to be expected.

69. The Thymatron ECT Devices failed to perform in a manner that a reasonable consumer would expect it to perform.

70. Defendant knew that the Thymatron ECT Devices manufactured, designed, labeled, promoted and/or sold by it, when used as Defendant promoted and instructed practitioners, was defective and dangerous in the manners hereinbefore described.

71. Defendant knew that, because said use was dangerous and defective, Thymatron ECT Devices could not be safely used for the purposes intended and promoted.

72. Defendant, knowing that said product when used as intended and promoted was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Plaintiff, when it placed the product in the stream of commerce without warning of the defects, and knew when so placed that it would be used without inspection for defects when so used.

73. By placing the Thymatron ECT Devices on the market and promoting their use, Defendant impliedly represented it was safe for the purposes intended and intended that medical facilities, purchasers, doctors, patients and members of the public rely on its misrepresentations.

74. As a direct and proximate result of one or more or all of the aforementioned unreasonably dangerous conditions, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement, and loss of a normal life. These losses are permanent.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AGAINST DEFENDANT SOMATICS

75. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

76. At all times relevant, Defendant SOMATICS, LLC designed, manufactured, marketed, sold, and/or distributed Thymatron ECT medical devices.

77. Defendant sold the subject ECT Device: the "Thymatron" ECT Device.

78. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether the Thymatron ECT Device was of merchantable quality and safe for its intended use.

79. Contrary to such implied warranty, and in violation of Mo. Rev. Stat. § 400.2-314, the Thymatron ECT Devices that Defendant manufactured, distributed, and sold, and which were used during Plaintiff's ECT treatment, was not of merchantable quality or safe for its intended use.

80. As a direct and proximate result of Defendant's breach of its implied warranty of merchantability, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement, and loss of a normal life. These losses are permanent.

COUNT IV
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AGAINST DEFENDANT SOMATICS

81. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

82. At all times relevant, Defendant SOMATICS, LLC designed, manufactured, marketed, sold, and/or distributed Thymatron ECT medical devices.

83. Prior to the time of sale, Defendant had reason to know that medical providers, including but not limited to Plaintiff's medical providers, would use Defendant's Thymatron ECT Devices on their respective patients, including but not limited to Plaintiff.

84. Patients, such as Plaintiff, including Plaintiff's medical providers, relied upon Defendant as the designer, manufacturer, distributor, and/or promoter of the Thymatron ECT Devices, to design, manufacture, label and distribute medical devices that were safe and effective

for the intended and/or promoted use.

85. In consideration, as part of the sale of the Thymatron ECT Devices, an implied warranty arose that the subject devices would be safe and suitable for the intended and promoted use.

86. In breach of this implied warranty of fitness for a particular purpose, and in violation of Mo. Rev. Stat. § 400.2-315, the Thymatron ECT Devices, were not delivered as warranted because they were not safe or effective for the intended and promoted use.

87. As a direct and proximate result of Defendant's breach of its implied warranty of fitness for a particular purpose, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement, and loss of a normal life. These losses are permanent.

COUNT V
BREACH OF EXPRESS WARRANTY
AGAINST DEFENDANT SOMATICS

88. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

89. At all times relevant, Defendant SOMATICS, LLC was the manufacturer, distributor, promoter, and seller of the Thymatron ECT Device.

90. SOMATICS expressly warranted to the public and the medical community, including Plaintiff's treating physicians and psychiatrists, that its Thymatron ECT Device was "the safest and most effective treatment for severe depression"; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar warranties of safety and efficacy.

91. The aforementioned representations, individually and collectively, were part of the basis of the bargain between Plaintiff (including her medical providers) and SOMATICS.

92. Plaintiff (including the medical community and her medical providers) directly and indirectly relied on the aforementioned representations by SOMATICS.

93. SOMATICS' aforementioned representations and warranties were false.

94. SOMATICS breached these express warranties, in violation of Mo. Rev. Stat. § 400.2-313, because:

a. There are no clinical trials or any other reliable evidence demonstrating that ECT treatment or treatment with the Thymatron ECT device is the safest and most effective treatment for severe depression;

b. Contrary to SOMATICS' warranties, ECT treatment and its Thymatron ECT Device, can and does cause brain injury;

c. Contrary to SOMATICS' warranties, ECT treatment and its Thymatron ECT Device, can and does cause permanent memory loss;

d. Contrary to SOMATICS' warranties, ECT treatment and its Thymatron ECT Device, can and does cause long-term and persistent effects on intellectual abilities or memories;

e. Contrary to SOMATICS' warranties, the truth is that the long-term efficacy and safety of ECT treatment has *never* been demonstrated.

95. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately suspended."[9]

96. As a direct and proximate result of SOMATICS' breach of its express warranties,

[9] John Read et al., *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).

Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement, and loss of a normal life. These losses are permanent.

COUNT VI
VIOLATION OF MISSOURI MERCHANDISING PRACTICES ACT AGAINST DEFENDANT SOMATICS

97. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

98. This Count is brought pursuant to the Missouri Merchandising Practices Act ("MMPA"), §§ 407.010, *et seq*., which provides in relevant part:

a. The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce … in or from the state of Missouri, is declared to be an unlawful practice. … Any act, use or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation.

99. At all relevant times, Plaintiff was a "person" within the meaning of Mo. Rev. Stat. § 407.010(5).

100. At all relevant times, Plaintiff purchased "merchandise" within the meaning of Mo. Rev. Stat. § 407.010(4) when she purchased medical services for ECT treatment.

101. At all relevant times, SOMATICS conducted "trade or commerce" within the meaning of Mo. Rev. Stat. § 407.010(7).

102. Defendant SOMATICS deliberately engaged in deceptive and unlawful marketing in violation of the Missouri Merchandising Practices Act by representing to the general public,

the medical community, including Plaintiff's medical providers that: its Thymatron ECT Device was "the safest and most effective treatment for severe depression"; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar warranties of safety and efficacy.

103. Plaintiff suffered an ascertainable loss in connection SOMATICS' sale or advertisement of its Thymatron ECT device. Plaintiff, the general public, and the medical community, including Plaintiff's medical providers, relied upon SOMATICS' deceptive and unlawful marketing practices, including, *inter alia*, the representation that its Thymatron ECT Device was safe and effective; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; and that its Thymatron ECT Device did not cause any long-term or persistent effects on cognitive abilities or memories.

104. Had SOMATICS not engaged in the deceptive conduct described herein, Plaintiff would not have consented to ECT treatment and would not have incurred related medical costs and injury.

105. SOMATICS' unfair and/or deceptive acts and/or practices violate the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.020.1.

106. As a direct and proximate result of SOMATICS' actions in violation of the Missouri Merchandising Practices Act, Plaintiff sustained an ascertainable loss, i.e., related medical costs and injuries, in an amount to be proven at trial.

COUNT VII
FRAUD
WILLFUL AND WANTON CONDUCT
AGAINST DEFENDANT SOMATICS

107. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

108. As a medical device company, SOMATICS had an affirmative duty to warn regarding all risks it knew, learned of, or should have known about associated with its medical

devices, including but not limited to, its Thymatron ECT Device.

109. SOMATICS knowingly and intentionally concealed adverse event information, and knowingly and intentionally provided misleading and inaccurate information that was material to medical providers and patients, which misled medical providers and patients who were relying directly and/or indirectly upon SOMATICS' representations and concealment.

110. SOMATICS' distribution of false and misleading information concerning the safety and efficacy of its Thymatron ECT devices as well as its intentional failure and refusal to properly test, study, report and investigate adverse events associated with its Thymatron ECT devices, caused health care providers, patients and the general public, including Plaintiff and her medical providers, to be misled about the risks and benefits of ECT therapy and the Thymatron ECT devices.

111. In addition to concealing and not reporting adverse events and risks, upon information and belief, SOMATICS made intentional affirmative misrepresentations to the public, patients, and the medical community, including Plaintiff's medical providers, that its Thymatron ECT Device was "the safest and most effective treatment for severe depression"; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar assurances of safety and efficacy.

112. Upon information and belief, when SOMATICS made these aforementioned representations and/omissions, it knew these representations and/or omissions were false or and/or wantonly and recklessly disregarded whether the representations and/or omissions were true. Upon information and belief, these representations and/or omissions were made by SOMATICS with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing hospitals, doctors, including Plaintiff's doctors and treaters, to use its Thymatron ECT Device and/or for patients, such as Plaintiff, to consent to ECT treatment.

113. SOMATICS made the aforementioned representations and/or omissions with the

intention and expectation that they would be relied upon by patients, doctors and the general public, including Plaintiff's doctors and patients such as Plaintiff.

114. Plaintiff (including the medical community and her medical providers) reasonably and justifiably relied on the aforementioned representations by SOMATICS.

115. SOMATICS' aforementioned representations were false and SOMATICS knew or should have known they were false. In reality, there are no clinical trials or any other reliable evidence demonstrating that ECT treatment or treatment with the Thymatron ECT device is the safest and most effective treatment for severe depression. Contrary to SOMATICS's statements, ECT treatment and its Thymatron ECT Device, can and does cause brain injury. Contrary to SOMATICS's representations, ECT treatment and the Thymatron ECT Device, can and does cause permanent memory loss. Contrary to SOMATICS's representations, ECT treatment and its Thymatron ECT Device, can and does cause long-term and persistent effects on intellectual abilities and memories. Contrary to SOMATICS's representations, the reality is that the long-term efficacy and safety of ECT treatment has *never* been demonstrated.

116. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately suspended."[10]

117. Had SOMATICS not made these false misrepresentations, omissions and concealments, and had it issued warnings to medical providers concerning the risks of brain injury, permanent cognitive impairment and permanent memory loss as well as the other serious adverse events associated with the ECT Thymatron Device, as well as the lack of demonstrated

[10] John Read et al., *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).

long-term safety and efficacy of its device, medical providers, including Plaintiff's medical providers, would have heeded these warnings and as is their fiduciary responsibilities, would have passed on those warnings to patients during the informed consent process. However, as a result of its willful, wanton, and fraudulent conduct, SOMATICS denied patients, including Plaintiff, the ability to make truly informed consent.

118. Had Plaintiff been warned concerning the risk of permanent brain injury or permanent neurocognitive decline and had he been warned about the lack of efficacy and safety for the long-term use of ECT, she would not have consented to any ECT treatment.

119. The actions and conduct of SOMATICS as alleged herein was wanton, grossly negligent and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiff in particular and to the public generally in that SOMATICS did willfully and knowingly falsely promote ECT treatment and its ECT Thymatron Device with the specific knowledge that its ECT Thymatron Device would be used without adequate instructions and warnings and without adequate knowledge regarding its efficacy, risk and long-term side effects.

120. The actions and conduct of Somatics as alleged herein was malicious, fraudulent, and oppressive toward Plaintiff in particular and the public generally, and SOMATICS conducts itself in a willful, wanton, and reckless manner.

121. As a direct and proximate result of SOMATICS' fraudulent statements and concealments, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement and loss of a normal life. These losses are permanent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant on all counts of the complaint, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For general damages, in an amount exceeding this Court's jurisdictional minimum and to be proven at the time of trial;
2. For specific damages, in an amount to be proven at the time of trial;
3. For medical, incidental, hospital, psychological care and other expenses, in an amount to be proven at trial;
4. For loss of earnings and earning capacity, in an amount to be proven at the time of trial;
5. For an award of pre- and post-judgment interest, as provided by law;
6. For exemplary or punitive damages, in an amount to be determined at the time of trial;
7. For an award providing for payment of costs of suit and attorneys' fees to Plaintiff, as provided by law;
8. For such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

DATED: January 27, 2021

Respectfully submitted,

BAUM HEDLUND ARISTEI & GOLDMAN

/s/ John A. Greaves

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